AUG 16 2005

K052038

53

510(k) SUMMARY

Submitter's Name and Address	Boston Scientific Corporation 3574 Ruffin Road San Diego, CA 92123
Contact Person	Renuka Krishnan Principal Specialist, Regulatory Affairs (858)503-1815
Common or Usual Name	PTA catheter
Product Code	LIT
Classification	Class II
Proprietary Names	Peripheral Cutting Balloon: small Monorail and Over-the-Wire Delivery Systems (PCB: small MR and OTW).

Predicate Devices
Boston Scientific small Peripheral Cutting Balloon; K051254
Boston Scientific 1 cm Peripheral Cutting Balloon; K051254 and K040155
Boston Scientific 2 cm Peripheral Cutting Balloon; K051254 and K041993

Device Description
The PCB: small MR and OTW features a balloon with 3 or 4 atherotomes (microsurgical blades) mounted longitudinally on its outer surface. When the PCB device is inflated, the atherotomes score the plaque, creating initiation sites for crack propagation. Percutaneous Angioplasty (PTA) with the PCB device allows dilatation of the target lesion with less pressure, minimizing barotrauma.

Radiopaque markers are placed on the guidewire tubing at the ends of the atherotomes to provide visual reference points for balloon positioning within the vessel. The Rated Burst Pressure (RBP) is 12 atm. The devices are available in nominal balloon diameters from 2.0 mm to 4.0 mm and 1.5 cm length (Table 1, p. 2).

Table 1. Model Numbers, PCB:small MR and OTW

Nom. Diameter (mm)	Over-the-Wire	Monorail
2.00	PCBO2015140F	PCBM2015140F
2.50	PCBO2515140F	PCBM2515140F
3.00	PCBO3015140F	PCBM3015140F
3.50	PCBO3515140F	PCBM3515140F
4.00	PCBO4015140F	PCBM4015140F

* Catheter length: 140 cm.

The OTW devices are attached to a Y-connector at one end; the MR is attached to a female luer. The catheter body for the PCB: small OTW has two lumens. The outer lumen is the balloon inflation lumen. The inner lumen is used to pass the catheter over a guidewire.

The proximal shaft for the PCB:small MR is a hypotube. This hypotube contains the balloon inflation lumen. The distal shaft is made of Pebax material and has a lumen for balloon inflation as well as a guidewire lumen. The guidewire lumen is colored green for ease of guidewire insertion. The guidewire exit port is 24 cm from the catheter tip. This port facilitates rapid exchange of the catheter. The PCB:small MR and OTW are coated with Bioslide BL at the distal section.

Intended Use

The Peripheral Cutting Balloons are indicated for Percutaneous Transluminal Angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

Substantial Equivalence

The PCB: small MR and OTW will incorporate a substantially equivalent design, fundamental technology and intended use as those featured in predicate devices.

Performance Testing

Bench testing and biocompatibility testing support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed devices have been designed and tested to assure conformance to the requirements for its intended use.

Conclusion

The PCB: small MR and OTW have been shown to be Substantially Equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2005

Boston Scientific Corporation
c/o Ms. Renuka Krishnan
3574 Ruffin Road
San Diego, CA 92123

Re: K052038
Peripheral Cutting Balloon Small Monorail Over-The-Wire
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: July 27, 2005
Received: July 28, 2005

Dear Ms. Krishnan:

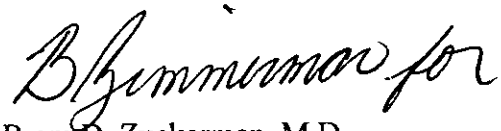
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K052038

Device Name: Peripheral Cutting Balloon™: small Monorail and Over-the-Wire Delivery systems

Indications For Use:

The Peripheral Cutting Balloon™ catheters are indicated for Percutaneous Transluminal Angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

Prescription Use: Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052038